UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI

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ARNOLD DEAN, INDIVIDUALLY, AND AS ADMINISTRATOR OF THE ESTATE OF NANCY DEAN,

Plaintiff,

-against-

BIOMET, INC., BIOMET ORTHOPEDICS, LLC, BIOMET U.S. RECONSTRUCTION, LLC, and BIOMET MANUFACTURING, LLC

Defendants.

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Docket No.:

COMPLAINT

JURY TRIAL DEMANDED

NOW COMES the Plaintiff, ARNOLD DEAN individually and as Administrator of the Estate of NANCY DEAN, by and through their attorneys, and for their causes of action, brings suit against the Defendants, Biomet Orthopedics, LLC; Biomet, Inc.; and Biomet, LLC, stating and averring as follows:

INTRODUCTION

1. This is a product liability case involving a defective hip implant system. Plaintiff's decedent, NANCY DEAN, had a Biomet M2a Magnum Metal-on-Metal Hip System ("The Device") implanted in her hip. The M2a Magnum Hip System is defective because excessive amounts of cobalt and chromium corrode and wear from the surfaces of the acetabular cup, the femoral head, and the taper sleeve. The excessive wear in turn causes the hip implant to fail and the surrounding tissue and bone to die. As a result of these defects, Ms. Dean's M2a Magnum Hip System failed in her body, causing toxic levels of cobalt and chromium, tissue and bone destruction, and the need for Ms. Dean to undergo a complicated and risky surgery to remove and replace the defective implant.

2. As a result of these defects, patients who have had the Devices implanted have endured, or will endure, unnecessary pain and suffering; debilitating lack of mobility; inflammation which can lead to damage or death of surrounding tissue and bone; and a subsequent more difficult revision surgery to replace the faulty Devices, giving rise to still more debilitation, a prolonged recovery time, and an increased risk of complications and death from surgery. Rather than recalling the Device upon receiving notice of complaints made to the United States Food and Drug Administration ("FDA") regarding the defects discussed above, or warning physicians and patients of these risks and precautions such as metal level monitoring, Defendants continued to aggressively market the Device, claiming it was a safe and effective hip replacement system.

3. Indeed, Defendants sought to capitalize on the problems with the competitor devices by asserting the superiority of the Device over other metal-on-metal hip implant designs sold by their competitors. The suffering and damages incurred by Plaintiffs herein could easily have been prevented. Plaintiff would not have suffered from unnecessary pain and debilitation, as well as the need to undergo subsequent revision surgery, had Defendants taken the affirmative step of recalling the Device (especially when dozens of complaints were first being made to the FDA regarding the Device's failures), or had Defendants at least warned the orthopedic surgical community and the public of the dangers of the Device so that those who had the Device implanted could be medically monitored for signs of the Device malfunctioning including loosening and metal debris related injury. Plaintiffs seek redress for Plaintiffs' injuries and associated damages that have been incurred as a result of those injuries.

4. This is a tag along action to the multi-district litigation over Biomet metal-on-metal hip implants which is styled *In Re: Biomet M2a Magnum Hip Implant Products Liability Litigation (MDL 2391)* pending in the United States District Court for the Northern District of

Indiana, South Bend Division, Cause No. 3:12-md-2391 before United States District Court Judge Robert L. Miller, Jr.

PARTIES

5. Plaintiff ARNOLD DEAN is a citizen of the United States and a resident of the state of Missouri. Mr. Dean resides in Rogersville, Webster County, Missouri. Before her passing, Plaintiff's Decedent NANCY DEAN was also a citizen of the United States and a resident of the state of Missouri, residing in Rogersville, Webster County, Missouri.

6. At all times relevant, Defendant, BIOMET, INC. was an Indiana Corporation with its principal place of business in Warsaw, Indiana.

7. Defendant BIOMET, INC. designed, manufactured, marketed, promoted, and sold the Device that was implanted into Plaintiff's body and is the subject of this action.

8. At all times relevant, Defendant, BIOMET ORTHOPEDICS, LLC was a limited liability company organized and existing under the laws of Indiana with its principal place of business in Warsaw, Indiana. The sole member of BIOMET ORTHOPEDICS, LLC is BIOMET, INC., which is incorporated in Indiana and has its principal place of business in Warsaw, Indiana.

9. At all relevant times, BIOMET ORTHOPEDICS LLC designed, manufactured, marketed, promoted, sold and introduced into interstate commerce, either directly or indirectly, the Biomet Hip Systems that are the subjects of this lawsuit.

10. Defendant BIOMET ORTHOPEDICS, LLC designed, manufactured, marketed, promoted, and sold the Device that was implanted into Plaintiff's body and is the subject of this action.

11. At all times relevant, Defendant, BIOMET U.S. RECONSTRUCTION, LLC was a limited liability company organized and existing under the laws of Indiana with its principal place

of business in Warsaw, Indiana. The sole member of BIOMET U.S. RECONSTRUCTION, LLC is BIOMET, INC., which is incorporated in Indiana and has its principal place of business in Warsaw, Indiana.

12. Defendant BIOMET U.S. RECONSTRUCTION, LLC designed, manufactured, marketed, promoted, and sold the Device that was implanted into Plaintiff's body and is the subject of this action.

13. At all times relevant, Defendant, BIOMET MANUFACTURING, LLC, f/k/a BIOMET MANUFACTURING CORP. was a limited liability company organized and existing under the laws of Indiana with its principal place of business in Warsaw, Indiana. The sole member of BIOMET MANUFACTURING, LLC is BIOMET, INC., which is incorporated in Indiana and has its principal place of business in Warsaw, Indiana.

14. Defendant BIOMET MANUFACTURING, LLC, f/k/a BIOMET MANUFACTURING CORP. designed, manufactured, marketed, promoted, and sold the Device that was implanted into Plaintiff's body and is the subject of this action.

15. Defendants, BIOMET, INC., BIOMET ORTHOPEDICS, LLC, BIOMET U.S. RECONSTRUCTION, LLC, and BIOMET MANUFACTURING, LLC are collectively referred to herein as "Biomet" or Defendants.

16. At all times relevant herein, Defendants were the agents of each other, and in doing the things alleged herein, each Defendant was acting within the course and scope of its agency and was subject to and under the supervision of each and every other Defendant herein. Specifically, each Defendant was but an instrumentality or conduit of the other in the prosecution of a single venture, namely the design, manufacture, promotion and sale of the M2a-38 Hip System and the M2a Magnum System. Therefore, it would be inequitable for either Defendant to escape liability

for any obligation of the other.

JURISDICTION AND VENUE

17. This is a civil action of which this Court has original jurisdiction under 28 U.S.C. Section 1332 because it is between citizens of different states and the amount in controversy exceeds the sum or value of $75,000, exclusive of costs and interest.

18. Venue is proper pursuant to 28 U.S.C. §1391(c) because Defendants are all corporations that have substantial, systematic, and continuous contacts in this District and they are all subject to personal jurisdiction in this District. Moreover, the Plaintiff and the Decedent's injuries occurred in this district. The Decedent's Biomet magnum M2a hip device was implanted in this district, and her explant/revision surgery occurred in this district.

FACTUAL BACKGROUND

A. The Biomet M2a Magnum Generally

19. The Biomet M2a Magnum Hip Systems that were implanted into the Plaintiff were developed for uncemented use in a total hip joint replacement. In a healthy hip, the hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is like a ball that fits into a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

20. These Biomet Systems consisted of a cobalt-chromium one-piece cup and a cobalt-chromium modular femoral head. This device is known as a "metal-on-metal" system due to the fact that both articulating surfaces, i.e. the metal acetabulum(cup) and femoral head (ball)-are both cobalt-chromium metal. These Devices were marketed with the claim that they would last much longer than the conventional hip implant with a polyethylene or plastic liner. Indeed, Defendants marketed the Device as having many advantages over other hip replacements or hip resurfacing

systems.

21. The metal-on-metal M2a Magnum System consisted of a cobalt-chromium one-piece cup and a cobalt-chromium modular femoral head. This device is known as a "metal-on-metal" system due to the fact that both articulating surfaces, i.e. the metal acetabulum (cup) and femoral head (ball)-are both cobalt-chromium metal.

B. Although Defendants' Hip System was a Class III device, it was cleared for Marketing as a Class II Device without premarket approval.

22. In 1976, the Medical Devices Amendment was passed, pursuant to which the FDA classified medical devices into three categories. A Class I category device poses almost no safety issues. A Class II category device poses moderate safety issues. A Class III device operates to sustain human life, is of substantial importance in preventing impairment of human health, or poses potentially unreasonable risks of harm to patients.

23. Generally, Class III devices must undergo the PreMarket Approval (PMA) process to be marketed in the United States. Premarket Approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, extensive clinical data to support the device's safety and effectiveness; a full statement of the device's components, ingredients, and properties, and of the principles of operation; a full description of the methods used in, and the facilities and controls used for, the design, manufacture, processing, and when relevant, packing and installation of, such device: samples or device components required by the FDA; and a specimen of the proposed labeling. When undergoing Premarket Approval, a Class III device may not use an existing device as a predicate, but rather the safety and effectiveness of the device must be independently shown.

24. The FDA may grant Premarket Approval only if it finds that there is reasonable assurance that the medical device is safe and effective, and must weigh any probable benefit to

health from the use of the device against any probable risk of injury or illness from such use.

25. The use of metal-on-metal hip joint replacement devices predates the Medical Device Amendments (MDA) of 1976. Metal-on-metal devices were formally classified into lass III on September 4, 1987. However, because these Class III devices predate the MDA, and because the FDA has neither called for a PMA nor down-classified these devices, metal-on-metal hip systems bypassed the rigorous scrutiny of the PreMarket Approval Process. Instead, they were and are "grandfathered in" and cleared for market through demonstrating substantial equivalence to other "predicate" metal-on-metal systems already on the market. This is the PreMarket Notification or 510(k) process by which a Class II, a less risky device, is cleared for market.

26. The metal-on-metal M2a Magnum System which is the subject of this lawsuit is a Class III medical device; however, it received clearance from the FDA through the 510(k) process generally reserved for Class II devices, which only requires a showing of substantial equivalence to a device already on the market. In obtaining clearance for marketing of this Hip System, Biomet bypassed the PreMarket Approval (PMA) process altogether.

27. Biomet applied for market clearance of its first metal-on-metal acetabular system on February 18, 2000 (Premarket Notification K993438), based upon substantial equivalence to four devices. Three of the four devices were components manufactured by Biomet and were used in metal/polymer systems, not metal-on-metal systems. The fourth predicate device, which was by Sulzer Orthopedics, was also not an exclusively metal-on-metal system, in that it included a plastic liner with a metal inlay. Although the Sulzer metal head interfaced with the metal inlay, Sulzer incorporated plastic in the shell liner, designed to dampen the load against the acetabulum.

28. Subsequent premarket notifications cleared additions and modifications to this device, including different shell/liner locking mechanisms, metal alloys, and sizes. 21. The

premarket notification for the M2a Acetabular System, submitted March 30, 2001 (KOllllO), introduced a one-piece cobalt chrome (CoCr) acetabular component with no liner. Substantial equivalence was based on earlier M2a systems, the DePuy Pinnacle Metal-on-Metal Acetabular System, and a first-generation metal-on-metal device, the McKee Farrar, a grandfathered Pre-Amendment Device known for early failures due to acetabular loosening.

29. On July 28, 2004, Biomet applied for market clearance of the M2a Magnum S stem (K042037), the Device at issue in this Complaint, based, in part, upon substantial equivalence to the M2a Acetabular System cleared via KOllllO, as well as two Wright Medical Technology one-piece CoCrMo acetabular shells. That 510K states that mechanical testing was performed to establish substantial equivalence to the predicate device, but no clinical testing was used. However, based upon substantial equivalence to predicate devices, clearance by the FDA for the M2a Magnum System was received on October 1, 2004.

C. Defendants knew or should have known that its metal-on-metal Hip Systems would lead to metallosis and other complications, but failed to subject the Devices to clinical testing prior to releasing it on the market.

30. While many hip replacements use an acetabular liner that fits inside the acetabular cup, the M2a Magnum Hip System does not. Instead, the System fits a metal femoral head directly into a one-piece metal acetabular cup, forcing metal-on-metal articulation with the full weight and pressure of the human body. This causes prosthesis-derived metal wear debris to be generated by mechanical wear, surface corrosion or a combination of both, in both particle and soluble forms. Corrosion products predominantly consist of metal oxides and hydroxides within the synovial fluid and peri-prosthetic tissues. Inside the hip joint, the metal reaction often causes fluids to accumulate and soft tissues and bone to die. If the metal fragments travel through the bloodstream, the patient can suffer systemic symptoms, such as extreme fatigue, headaches, and other chronic ailments.

31. In 1996, Jonathan Black, Ph.D., an industry consultant and Clemson professor emeritus of bioengineering who specialized in production and biological sequelae of wear debris, warned in a medical journal article that metal-on-metal designs posed significant risks because little was known about the biological havoc that metallic debris might cause. Dr. Black also argued that, given the high success rate of existing designs, it would be statistically impossible to run enough studies to prove the new implants' supposed superiority.

32. In the November 1, 2001 issue of The Journal of Bone and Joint Surgery, Issue 83, S68-72, Dr. Seth Greenwald and Dr. Jonathan Garino, echoed Dr. Black's fear regarding the longer-term concern about metal particle and ion generation, citing increased chromium concentrations at the time of long-term follow-up of McKee-Farrar implant patients.

33. In 2003, the British Journal of Bone and Joint Surgery reported the work of Clarke, Lee, Arora and Villar who found that large diameter metal on metal bearing result in a greater systemic exposure of cobalt and chromium ions.

34. In its July 2005 issue, The Journal of Bone and Joint Surgery published the results of a study that retrospectively analyzed 165 patients (169 hips) who had undergone primary cementless total hip replacement with a contemporary metal-on-metal total hip design between 2000 and 2002. The findings of the study raised the fear that early osteolysis in patients with this second-generation metal-on-metal hip replacement is associated with abnormalities consistent with delayed-type hypersensitivity to metal.

35. Had Defendants heeded Dr. Black's warning and the warnings published thereafter, and closely monitored the performance of second generation metal-on-metal systems and the post-market experience of the metal-on-metal M2a Hip Systems, they would have discovered that the Devices result in a high percentage of patients developing metallosis, biologic toxicity and an early

and high failure rate due to the release of metal particles in the patients' surrounding tissue when the cobalt-chromium metal femoral head rotates with the cobalt-chromium metal acetabular liner.

36. The formation of metallosis, pseudotumors, and infection and inflammation causes severe pain and discomfort, death of surrounding tissue and bone loss, and lack of mobility. It further makes revision surgery exponentially more difficult to perform.

37. At all relevant times, Defendants were aware that the metal-on-metal M2a Magnum Hip System posed an unreasonably high risk of developing metallosis, biologic toxicity, and total hip failure, and Defendants were aware that the Device resulted in unsafe release of toxic metal ions into the tissues and bloodstream of the hip implant recipients.

38. Despite public knowledge to the contrary, Defendants have misrepresented, and continue to misrepresent the metal-on-metal M2a Magnum System not only as high-quality, safe and effective hip replacement products, but also as highly superior to other metal-on-metal hips on the market.

39. For example, Biomet published marketing brochures touting the safety and durability of the M2 Magnum Hip System, claiming that it was superior to other safer hip implants on the market, stating:

> "The M2a-MagnumTM Large Metal Articulation System offers optimal joint mechanic restoration and ultra low -wear rates in vivo. Many studies conducted over the last several decades have shown no definitive correlation of negative health issues to ion levels exhibited from metal-on-metal implants."

40. These brochures were given to doctors around the world, including Plaintiff's orthopedic surgeon, to encourage them to use the M2a Magnum Hip System.

41. Further, Biomet represented as recently as December, 2011 in the Journal of

Arthoplasty:

> Well-designed metal-on-metal (MoM) hips are good options for many patients. However, design features in certain MoM components have led to increased failure rates. Biomet's M2a-Magnum System delivers a clinically proven, unique design that has shown a statistically significant lower revision rate than other MoM implants.
>
> M2a-Magnum System:
>
> - Lowest cobalt ion levels in a peer-reviewed, head-to-head study of four MoM implant designs;
> - Over 98% median reported survivorship at three years;
> - In over 10,000 cases, revision rate is less than 2.5%;
> - Similar revision rate to metal-on-poly in the Australian and New Zealand NJR (2.6% and 2.9%)
> - Statistically significant lower revision rate than other MoM constructs in the New Zealand NJR (3.9%)"

42. Until at least 2014, Defendants continued to sell the M2a Magnum Hip Systems to doctors who implanted them in countless numbers of patients with an unreasonably high percentage of those patients being forced to endure serious injury from metallosis, pseudotumors, and biologic toxicity, revision surgery and other complications.

D. Federal Requirements

43. Pursuant to federal law, a device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packaging, storage or installation are not in conformity with federal requirements. See 21 U.S.C. 351.

44. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular manner, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. 352.

45. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by the FDA. These regulations require manufacturers to meet design control requirements, including but not limited to, conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production. Manufacturers must establish and maintain procedures for implementing corrective actions and preventative actions, and investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary and are required to use statistical techniques where necessary to evaluate product performance. See 21 CFR 820.

46. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR 820 et seq. as explained in the Federal Register, because the Current Good Manufacturing Practice (CGMP) regulations must apply to a variety of medical devices, the regulations do not prescribe the details for how a manufacturer must produce a device. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured, and the manufacturing processes employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with, and implement, the basic requirements set forth in the quality system regulations.

47. Pursuant to 21 CFR 820.1(c), the failure to comply with any of these provisions in Part 820 renders a device adulterated under section 501 (h) of the Federal Food, Drug & Cosmetic Act ("the Act")(21 U.S.C. 351).

48. Defendants' metal-on-metal M2a Magnum Systems are adulterated pursuant to 21

U.S.C. 351 because, among other things, they failed to meet established performance standards, in that they caused severe injuries to recipients of the Device, including metallosis, pseudotumors, osteomyelitis, loosening of the components, and other conditions, which often required premature, painful revision surgery.

49. In addition, Defendants' metal-on-metal M2a Magnum Systems are misbranded because, among other things, they cause severe injuries to the recipients of the Devices when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. 352.

50. As a result of the foregoing symptoms, revision surgeries have been necessary to remove the faulty Devices from a number of patients. These revision surgeries present enormous risks to the patients because they are technically more difficult than the original surgery to implant the Device, the patient is more at risk of complications and death, and the recovery time is prolonged as compared to the original hip replacement surgery. Further, as a result of metallosis and bone and soft tissue destruction, patients who have been implanted with the Device and undergone a revision surgery for premature failure of the Device are less likely to have successful hip implantation surgeries in the future and face an extremely high post-operative complication rate following revision surgeries to remove a defective Device.

E. Plaintiff's M2a-Magnum Device

51. On or about March 18, 2010, Plaintiff underwent a right hip replacement surgery, during which a Biomet metal-on-metal Magnum prosthesis was implanted in her body. During that procedure, Plaintiff was implanted with the following hip implant products manufactured and marketed by Defendants herein: Biomet Orthopedics M2a Magnum acetabular shell size 48-mm, a latereralized Taperloc Stem 7.5 mm, and a Biomet Magnum femoral head size 42 mm diameter, -3 neck length.

52. After the surgical implantation of the Magnum Device, Plaintiff's decedent suffered symptoms including but not limited to increasingly debilitating pain, discomfort, and soreness.

53. Plaintiff additionally suffered or incurred the following personal and economic injuries as a result of the implantation with the Magnum Device:

a. underwent an additional surgical procedure that would not have been needed if the Magnum Device had performed satisfactorily during its expected usual life;

b. permanent harm by severe metal poisoning and metallosis from the metal debris of the Magnum Device;

c. lost wages and future loss of earning capacity;

d. medical expenses and will incur additional medical expenses in the future; and

e. permanent harm because of complications normally associated with a second hip replacement.

54. On July 14, 2014, Plaintiff underwent a complex, risky, and painful surgery (known as a "revision surgery") to remove the failed M2a Magnum Hip System from her body. Revision surgeries are generally more complex than the original hip replacement surgery, often because there is a reduced amount of bone in which to place the new hip implants. Revision surgeries also usually take longer than the original hip replacement surgery and the revision surgery has a higher rate of complications.

55. An employee and/or agent of Defendants provided the Device to Plaintiff's original implanting surgeon at the time of the original surgery to implant the Device as noted herein.

56. Beyond merely providing the Device to the surgeon, agents of Defendants were hired by Defendants to aggressively promote, distribute, and sell the Device.

57. Directors, managers, and sales representatives of Defendants received training and education from Defendants, including orthopedic and surgical training, product design rationale for the Device, education regarding proper use of the tools to implant the Device, selection of complementary components to the Device, and training on how to sell the Device to surgeons over hip replacements offered by competitors.

58. On numerous occasions, Defendants met with orthopedic surgeons, including, on information and belief, with Plaintiff's orthopedic surgeon who performed the original implantation surgeon on Plaintiff, to promote the Device.

59. At some or all of these meetings, one or more representatives of Defendants were present. During these meetings, Defendants assured the orthopedic surgeons, including (upon information and belief) Plaintiff's original implanting orthopedic surgeon, that the Device was safe, effective, one of the best products on the market, had an excellent track record, had very low wear, would last longer than traditional hip implants, and had a low and acceptable failure rate.

60. Defendants continued to "defend" the Device even after Defendants became aware of numerous and serious complications with it.

61. Further, Defendants did not reveal (and instead concealed) their knowledge of numerous and serious complications and other "bad data" during their meetings with orthopedic surgeons, including Plaintiff's original implanting orthopedic surgeon.

62. All of the injuries suffered by the Plaintiff were caused by the defective design, warnings, construction and unreasonably dangerous character of the M2a Systems that were implanted into her. Had Defendants not concealed the known defects, the early failure rate, the known complications and unreasonable risks of metallosis and failure associated with the use of the

metal-on-metal M2a Hip Systems, Plaintiff would not have consented to the metal-on-metal M2a Magnum Hip Systems to be used in her total hip replacements.

63. Plaintiff's revision surgery has subjected Plaintiff to much greater risks of future complications than Plaintiff had before the revision surgery. For example, several studies have found that a revision surgery causes a much higher risk of dislocation compared with an original hip replacement surgery. In one study conducted by Charlotte Phillips and her colleagues at Brigham and Women's Hospital in Boston, 14.4% of patients who underwent a revision surgery suffered from a dislocation compared with 3.9% of patients who underwent an original hip replacement surgery. In other words, hip replacement patients who have undergone a revision surgery are almost four times more likely to suffer from a hip dislocation than those who have not. (Phillips CB, *et al.* Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. *American Journal of Bone and Joint Surgery* 2003; 85:20-26.)

64. Upon information and belief, Defendants were instrumental in educating Plaintiff's original implanting orthopedic surgeon regarding claimed advantages of the product, addressing the questions of the surgeon and providing information that the surgeon could, in turn, share with patients such as Plaintiff herein who were contemplating hip implant surgery and making decisions regarding the type of product to be utilized for such a procedure.

65. Had Plaintiff or Plaintiff's surgeon known that the Device caused injury, posed serious safety risks, that its risks outweighed its benefits, that far safer and reliable alternatives were available, and/or the likelihood of premature device failure and the need for early revision surgery to remove the defective Device, neither Plaintiff and/or Plaintiff's original implanting surgeon would have chosen the Device for the initial hip implant surgery. Rather, Plaintiff and/or Plaintiff's

original implanting surgeon would have opted for the safer and more effective traditional hip implant models.

66. As a direct and proximate result of Defendants placing the defective Device into the stream of commerce, Plaintiff has suffered, and continues to suffer, injuries and damages including, but not limited to, the following: past, present, and future physical and mental pain and suffering; past, present, and future expenses for medical, rehabilitation, and nursing care; loss of earnings and the capacity to earn a living; and loss of the quality of life. Plaintiff's spouse has suffered in the past and will continue to suffer in the future injuries and damages due to a loss of consortium as a result of injuries sustained by Plaintiff. These injuries and damages are continuing.

COUNT I
STRICT LIABILITY FOR DESIGN DEFECT

67. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

68. At all times herein mentioned, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed into the stream of commerce, the Device that was surgically implanted in Plaintiff herein.

69. At all times herein mentioned, the Device was in an unsafe, defective, and inherently dangerous condition for users such as Plaintiff herein in whom the Device had been surgically implanted.

70. The Device was in an unsafe, defective, and inherently dangerous condition at the time it left Defendants' possession.

71. At all times herein mentioned, the Device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product, including Plaintiff herein, without substantial change in the condition in which the Device was designed, produced,

manufactured, sold, distributed, and marketed by Defendants.

72. The Device's unsafe, defective, and inherently dangerous condition was a cause of injury to Plaintiff herein.

73. The Device failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

74. The injuries to Plaintiff herein resulted from use of the Device in a manner that was both intended and reasonably foreseeable by Defendants.

75. At all times herein mentioned, the Device posed a risk of dangers inherent in the design which outweighed the benefits of such design of the Device for patients including Plaintiff herein.

76. At all times herein mentioned, the Device was defective and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by Defendants.

77. At all times herein mentioned, Defendants knew, or should have known, that the Device was in a defective condition, and was and is inherently dangerous and unsafe to patients such as Plaintiff herein.

78. At the time of the implantation of the Device into Plaintiff herein, the aforesaid Device was being used for the purposes and in a manner normally intended, namely for use as a hip replacement device.

79. Defendants, with this knowledge, voluntarily designed their Device in a dangerous condition for use by the public, including Plaintiff herein.

80. Defendants had a duty to Plaintiff and other patients to create a product that was not unreasonably dangerous for its normal and intended use.

81. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, including Plaintiff herein, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff as a result of implantation of the defective Device.

82. As a direct and proximate result of Defendants' placement of the defective Device into the stream of commerce, Plaintiff experienced and/or will experience severe harmful effects, which are permanent and lasting in nature, including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

83. Further, as a result of the foregoing acts and omissions, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

84. As a proximate cause of Biomet's wrongful conduct, Plaintiff suffered injuries and damages as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants in an amount in excess of $75,000.00, together with the costs of this action, post-judgment interest, and such other relief as this Court deems just.

COUNT II
STRICT LIABILITY FOR INADEQUATE WARNING

85. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

86. At all times herein mentioned, Defendants designed, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed into the stream of commerce the Device that was surgically implanted in Plaintiff herein.

87. The M2a Magnum Systems that were implanted into the Plaintiff were defective and unreasonably dangerous when they left the possession of the Defendants in that:

a. The device contained insufficient warnings to alert consumers and their prescribing physicians that the System posed an unreasonably high risk of failure once implanted;

b. Defendants' promotional materials, labeling and instructional materials that accompanied the System were inadequate and misleading to consumers and their prescribing physicians;

c. Even after Defendants received notice from reputable medical sources prior to the sale of the device to the Plaintiff, that the device presented an inordinately high risk of failure and harm to the consumer, Defendants knowingly and deliberately failed to warn the public, including Plaintiff and her prescribing physician, of the serious risk of injury and failure occasioned by the defects in the device;

d. The System did not conform to the representations made by Defendants concerning the device;

e. Defendants' representations concerning the System did not conform to applicable federal requirements.

88. The Defendants, as manufacturers of the M2a Magnum System, are held to the level of knowledge of experts in the field of that type of prosthetic devices, and had a duty to warn their consumers and prescribing physicians of the dangers associated with the devices and failed to do so.

89. At the time Plaintiffs physician prescribed and implanted the M2a Systems, the physician did not have substantially the same knowledge as the Defendants about the unreasonably high risks of failure of the devices because Defendants failed to provide adequate warnings of those risks to her or her implanting physician.

90. The Device was defective due to inadequate warnings, as Defendants knew or

should have known that the Device could fail early in patients, including Plaintiff herein, and therefore give rise to physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the Device with the attendant risks of complications and death from such further surgery, but failed to give consumers, such as Plaintiff, adequate warning of such risks.

91. The Device is unsafe and inherently dangerous due to inadequate warnings because it was sold to Plaintiff without adequate warnings regarding the following unsafe conditions, propensities, and risks of the Device: to loosen and cause serious pain and necessitate additional surgery; to generate metal debris resulting in metallosis and increased cobalt and chromium levels; to cause damage to soft tissue and bone; to subject the patient to possible cancer and other potential harm due to elevated metal ions and metallosis.

92. The Device was defective, unsafe, and inherently dangerous due to inadequate warnings at the time that it left Defendants' possession and was placed into the stream of commerce.

93. At all times herein mentioned, the Device and its associated instructions and warnings were expected to and did reach the usual consumers, handlers, and persons coming into contact with said product, including Plaintiff herein, without substantial change in the condition in which the Device and its associated instructions and warnings were designed, produced, manufactured, sold, distributed, and marketed by Defendants.

94. The Device's unsafe, defective, and inherently dangerous condition due to inadequate warnings and instructions were the cause of injury to Plaintiff herein, and those injuries were reasonably foreseeable by Defendants.

95. As a direct and proximate result of Defendants' placement of the Device with its inadequate and defective warnings and instructions for use into the stream of commerce, Plaintiff

experienced and/or will experience severe harmful effects, which are permanent and lasting in nature, including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

96. Further, as a result of the foregoing defects in the instructions and warnings that accompanied the Device, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

WHEREFORE, Plaintiff demands judgment against Defendants in an amount in excess of $75,000.00, together with the costs of this action, post-judgment interest, and such other relief as this Court deems just.

COUNT III
STRICT LIABILITY FOR MANUFACTURING DEFECT

97. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

98. At all times herein mentioned, Defendants designed, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed into the stream of commerce the Device that was surgically implanted in Plaintiff herein.

99. The Device that was surgically implanted in Plaintiff was defective in its manufacture when it left the hands of Defendants in that the Device deviated from product specifications and/or performance standards of the manufacturer and posed a serious risk that the Device could fail early in patients, such as occurred when the Device was implanted in Plaintiff herein, therefore giving rise to physical injury, pain and suffering, debilitation, and the need for a

revision surgery to replace the Device with the attendant risks of complications and death from such further surgery.

100. As a direct and proximate result of Defendants' placement of the defective Device into the stream of commerce, Plaintiff experienced and/or will experience severe harmful effects, which are permanent and lasting in nature, including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

101. Further, as a result of the foregoing acts and omissions and manufacturing defects in the Device, Plaintiff has suffered and/or will in the future suffer lost wages and diminished capacity to earn wages.

WHEREFORE, Plaintiff demands judgment against Defendants in an amount in excess of $75,000.00, together with the costs of this action, post-judgment interest, and such other relief as this Court deems just.

COUNT IV
BREACH OF EXPRESS WARRANTY

102. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

103. At all times herein mentioned, Defendants designed, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed into the stream of commerce the Device that was surgically implanted in Plaintiff herein.

104. Defendants expressly warranted the following: that the Device was a safe and

effective hip replacement implant; that the Device would last longer than a traditional polyethylene-lined implant, and that the longer lifespan of the Device made it more appropriate for implantation in young and active patients, such as Plaintiff herein.

105. Indeed, as set forth in detail above, Defendants made numerous representations about the quality, safety, effectiveness, and expected lifespan of the Device which form express warranties to consumers, including Plaintiff herein.

106. The Device, when placed into the stream of commerce by Defendants, did not conform to these express representations because the Device failed prematurely, thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the Device with the attendant risks of complications and death from such further surgery.

107. As a direct and proximate result of Defendants' breach of express warranties regarding the safety and effectiveness of the Device, Plaintiff experienced and/or will experience severe harmful effects, which are permanent and lasting in nature, including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

108. Further, as a result of the foregoing acts and omissions and breach of express warranties regarding the safety and effectiveness of the Device, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

WHEREFORE, Plaintiff demands judgment against Defendants in an amount in excess of $75,000.00, together with the costs of this action, post-judgment interest, and such other relief as this Court deems just.

COUNT V
NEGLIGENCE

109. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

110. Defendants had a duty to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, selling, testing, assuring quality, and/or distributing the Device into the stream of commerce, including a duty to assure that the Device would not cause patients in whom the Device was surgically implanted, such as Plaintiff herein, to suffer harmful effects and injuries caused by the Device.

111. Defendants failed to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, selling, testing, assuring quality, and/or distributing the Device into the stream of commerce in that Defendants knew or should have known that patients who were surgically implanted with the Device, including Plaintiff herein, were at risk for suffering harmful effects and injuries caused by the Device including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

112. The negligence of Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Negligently designing the Device in a manner which was dangerous to those individuals who had the Device surgically implanted, including Plaintiff herein;

b. Designing, manufacturing, producing, creating, and/or promoting the Device without adequately, sufficiently, or thoroughly testing it;

c. Failing to conduct sufficient testing programs to determine whether or not the aforesaid Device was safe for use in patients such as Plaintiff herein;

d. Failing to inform patients, including Plaintiff herein, and surgeons, including Plaintiff's original implanting surgeon, that the Device was unsafe and unfit for use due to its defective condition, inherently dangerous, dangerous beyond the extent that would be contemplated by an ordinary consumer with ordinary knowledge as to the Device's characteristics, and the fact that the risks of use of the Device outweighed the Device's benefits;

e. Selling the Device without making proper and sufficient tests to determine the dangers that the Device posed to patients, including Plaintiff herein;

f. Negligently failing to adequately and correctly warn Plaintiff or Plaintiff's physicians, hospitals and/or healthcare providers of the dangers of Device;

g. Negligently failing to recall their dangerous and defective Device at the earliest date that it became known that the Device was, in fact, dangerous and defective;

h. failing to provide adequate instructions regarding safety precautions to be observed by surgeons who would reasonably and foreseeably come into contact with, and more particularly, implant the Device into their patients;

i. Negligently advertising and recommending the use of the Device despite the fact that Defendants knew or should have known of its dangerous propensities;

j. Negligently representing that the Device offered was safe for use for its intended purpose, when, in fact, it was unsafe;

k. Negligently manufacturing the Device in a manner which was dangerous to those individuals who had it implanted, including Plaintiff herein;

l. Negligently producing the Device in a manner which was dangerous to those individuals who had it implanted, including Plaintiff herein;

m. Negligently assembling the Device in a manner which was dangerous to those individuals who had it implanted, including Plaintiff herein;

n. Under-reporting, under-estimating, and downplaying the serious dangers associated with use of the Device;

o. Negligently designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing, and/or sale of the Device in that they failed use due care in designing and manufacturing the Device so as to avoid the aforementioned risks to patients who had the Devices surgically implanted, including Plaintiff herein;

p. Negligently designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing, and/or sale of the Device in that they failed to accompany the Device with proper warnings and instructions for use;

q. Negligently designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing, and/or sale of the Device in that they failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the Device;

r. Acting with willful, reckless and wanton misconduct in allowing the dangerous and defective Device to be implanted in patients, including Plaintiff herein, without sufficient testing and with express knowledge of enhanced risks, and

s. Otherwise acting with careless and/or negligent disregard for the health and safety of patients, including Plaintiff herein.

113. Despite the fact that Defendants knew or should have known that the Device caused harm to patients in whom the Device was surgically implanted, including Plaintiff herein, Defendants continued to market, manufacture, distribute, and/or sell the defective and unreasonably dangerous Device.

114. Defendants knew or should have known that consumers such as Plaintiff would suffer foreseeable injury and/or be at risk of suffering injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

115. Defendants' negligence was the proximate cause of Plaintiff's physical, mental, and emotional injuries and harm, and economic losses which Plaintiff has suffered and/or will continue

to suffer.

116. As a direct and proximate result of Defendants' failure to exercise ordinary care and negligent acts as outlined above with regard to placement of the defective Device into the stream of commerce, Plaintiff experienced and/or will experience severe harmful effects, which are permanent and lasting in nature, including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

117. Further, as a result of the foregoing failure to exercise ordinary care and negligent acts of Defendants, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

WHEREFORE, Plaintiff demands judgment against Defendants in an amount in excess of $75,000.00, together with the costs of this action, post-judgment interest, and such other relief as this Court deems just.

COUNT VI
NEGLIGENT MISREPRESENTATION

118. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

119. Defendants supplied false information to the patients, including Plaintiff herein, and to surgeons, including Plaintiff's surgeons, regarding the claimed superior quality, safety, and effectiveness of the Device. Defendants provided this false information to induce patients, including Plaintiff herein, and surgeons, including Plaintiff's original implanting surgeon, to purchase and implant the Device.

120. Defendants knew or should have known that the information that Defendants supplied regarding the purported superior quality, safety, and effectiveness of the Device would induce Plaintiff and Plaintiffs physicians to purchase and use the Device and that such information was false and misleading.

121. Defendants were negligent in obtaining or communicating false information regarding the purported superior quality, safety, and effectiveness of the Device.

122. Plaintiff and Plaintiff's physicians relied on the false information supplied by Defendants to Plaintiff's detriment in that such false information led to the purchase of the Device and implantation of the Device into Plaintiff's body, which have subsequently caused severe injury and catastrophic damages to Plaintiff.

123. Plaintiff and Plaintiff's physicians were justified in their reliance on the false information supplied by Defendants regarding the purported superior quality, safety, and effectiveness of the Device.

124. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff experienced and/or will experience severe harmful effects, which are permanent and lasting in nature, including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

125. Further, as a result of the foregoing negligent misrepresentations, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

WHEREFORE, Plaintiff demands judgment against Defendants in an amount in excess of

$75,000.00, together with the costs of this action, post-judgment interest, and such other relief as this Court deems just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment for the following:

a) Past and future lost wages, medical, permanency and incidental expenses, according to proof;

b) Past and future general damages for pain and suffering, according to proof;

c) Punitive and exemplary damages in an amount to be determined at trial;

d) Prejudgment and post judgment interest;

e) Costs to bring this action; and

f) Such other and further relief as the court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury on all issues raised herein.

Dated: July 10, 2019

By: /s/ Christopher L. Schnieders
Christopher Schnieders, MO Bar # 57725
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